

Claims 2 and 6-18 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. In response, claims 1-4, 6, 8-13, and 18 have been amended to more particularly define the invention.

## ***II. Rejections under 35 U.S.C. § 102(b)***

### ***A. Ricciardone et al.***

Claim 1 is rejected under 35 U.S.C. § 102(b) as being anticipated by Ricciardone, et al.

The Examiner states:

[Claim 1] is drawn to a method comprising: collecting known biological samples, and adding at least one known DNA fragment into the samples.[...]

Ricciardone et al. also discloses standard PCR reactions, in which known biological samples are prepared and primers (DNA of known length and sequence) are added to said samples.

Applicants traverse. Ricciardone et al. describes the simple analysis of STR loci in the normal course of genotyping. For example, claim 1 of Ricciardone et al. discloses the addition of unique DNA molecule(s), which will stand out from the resident milieu of DNA molecules during the course of standard analyses. Thus, Ricciardone et al. does not address the issue of marking samples. Rather, this publication describes methodology for analyzing the genetic composition of samples.

Claim 1, as amended, defines a process for marking biological samples by way of a DNA fragment which does not interfere with subsequent nucleic acid analysis of the biological sample.

Applicants respectfully submit that the combination of recitations in claim 1 is patentable over the applied art of record, when the claims is interpreted as a whole.

### ***III. Rejections under 35 U.S.C. § 103(a)***

#### ***A. Dollinger***

The Examiner states that claims 1-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dollinger. (U.S. 5,451,505). The Examiner states:

One of ordinary skill in the art would have been motivated to apply the taggant methodology of Dollinger to biological samples because this would have clearly been a straightforward, logical application. It was well known and common knowledge in the art that care must be taken with biological samples so as not to contaminate or mix up said samples, particularly with respect to critical situations such as forensic samples wherein analysis may have important consequences. Dollinger clearly discloses that taggants can be used with "any substance", and that the particular applications which are discussed in the patent "are not meant to be limiting, but will serve to offer those of skill an understanding of the versatility of this invention".

However, Applicants respectfully submit that the Examiner has not cited to any prior art to support his contention. Indeed, the Examiner has neither cited to art that would have suggested to those of ordinary skill in the art that they should carry out the claimed process, nor cited to art that would have revealed that in so carrying out the process, one of ordinary skill would have a reasonable expectation of success. *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991). The focus of the inquiry must be upon whether the invention was obvious to one of ordinary skill in the art at the time the invention was made. The luxury of hindsight is not permitted.

The test under 35 U.S.C. § 103 is whether the claimed invention considered as a whole, would have been obvious. The invention as a whole is not restricted to the specific subject matter claimed, but also embraces its properties and the problem it solves. *See, In re Wright*, 6 U.S.P.Q.2d 1959 (Fed. Cir. 1988). Applicants have provided a means for ensuring the integrity of a biological sample, thereby solving a problem that was neither disclosed nor envisioned by Dollinger. The

DNA marker described by Applicants is detected during the course of analysis of the biological samples and is detected by the same method of analysis used to examine the biological sample, at the same time. This concurrent analysis is critical, as it ensures sample integrity. Dollinger does not disclose concurrent analysis. In Dollinger the separate timing of analysis of the tagged substance (if indeed there is such analysis) and the marker, could allow for confusion of multiple samples, whether inadvertently or advertently.

In order to provide for concurrent analysis, the marker used in the present invention had to be completely compatible with the method(s) of analysis of the biological sample. As Dollinger did not contemplate the tagging of biological samples for subsequent analysis, this constraint did not apply. In Dollinger any analysis of the sample is separate from analysis of the tag and could be done separately. Thus, in Dollinger the analysis does not have to preserve sample integrity. For example, extracting DNA from a marked aliquot of a pharmaceutical for PCR analysis may destroy the pharmaceutical, while analysis of drug composition of the pharmaceutical may destroy the DNA additive. As the analyses are done in parallel, compatibility of methodology is not a required feature of Dollinger.

The method disclosed by Dollinger is related to conventional taggants used with compounds such as explosives. Contrarily, applicants invention provides a means for quality control, it ensures the fidelity of the methods of handling and analysis of forensic and related applications.

Reconsideration of the above rejection and withdrawal thereof is respectfully requested.

### ***CONCLUSION***

Applicants respectfully submit that the arguments and amendments to the claims set forth herein place the instant Application in condition for allowance. No new matter has been entered, and amended claims 1-4, 6, 8-13, and 18 are supported by the Specification as originally filed. Accordingly, Applicants respectfully requests that this Application be allowed to pass to issue.

## *AUTHORIZATION*

The Commissioner is hereby authorized to charge any additional fees which may be required for this Amendment, or credit any overpayment to deposit account no. 50-0436.

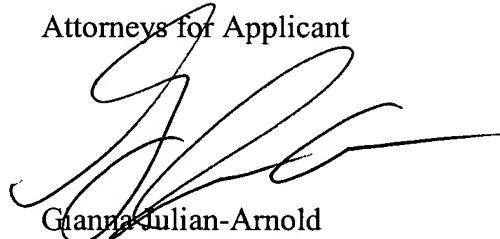
In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to deposit account no. 50-0436.

Should any further questions arise concerning this Application, or if the Examiner believes that a telephone or in-person conference would further the prosecution of this Application, the Examiner is invited to call the Applicants' attorney at the number listed below.

Respectfully submitted

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